REMARKS/ARGUMENTS

Initially, Applicant would like to express appreciation to the Examiner for the detailed Official Action provided.

Claims 1-22 are currently pending. Applicant respectfully requests reconsideration of the outstanding rejections, and allowance of all the claims pending in the present application.

In the Official Action, the Examiner rejected claims 1, 3 and 8-14, under 35 U.S.C. § 102(b) as being anticipated by HOFFMAN et al. (U.S. Patent No. 5,021,056); and

Claims 15 and 17 have been rejected under 35 U.S.C. § 102(e) as being anticipated by HUEBNER et al. (U.S. Pub. 2004/0102788).

Applicant respectfully traverses the above-noted rejections.

In this regard, Applicant submits that HOFFMAN and HUEBNER do not disclose each and every element as recited in claims 1 and 15, respectively.

In particular, claims 1 and 15 both generally recite a device for ligament reconstruction including, inter alia, a connector which connects the rear-end and the tip...and the rear-end being configured to drive the tip and connector into a bone.

Applicant submits that neither HOFFMAN nor HUEBNER discloses the abovenoted combination of elements.

Initially, Applicant submits that, in setting forth the above-noted rejections, the Examiner merely repeats the statement of the rejection as contained in the Official Action dated March 30, 2007. However, the Examiner does not explain how or where either HOFFMAN or HUEBNER discloses the rear-end of the ligament reconstruction device

being configured to drive the tip and connector into a bone, as generally recited in independent claims 1 and 15.

Contrary to the Examiner's assertions, Applicant again submits that the device of HOFFMAN is structurally very different from the presently claimed invention.

In particular, Applicant submits that HOFFMAN discloses that the "transverse alignment or first guide assembly 10 is positioned mediolaterally on the upper tibia 138, as shown in FIG 25, with the upper end of the assembly touching the tibial locating needles. The clamp arm 44 can be swung to a position almost normal to the clamp arm 42, by virtue of the slot 30, in order to facilitate this mounting of the assembly on the tibia. The two clamp plates 54, 56 are brought into engagement with opposite sides of the tibia by rotation of the knobs 34, 36 driving cylinders 50, 52 along the threaded shaft 32. The clamp plates are tightened until the assembly is firmly positioned on the tibia with the protrusions 68 providing a biting grip. The assembly is stabilized by drills 19 inserted into the bone through holes 64. Next a transverse bore is drilled completely through the tibia using one of the guide holes 62" (see, Column 5, lines 3-19).

In other words, Applicant submits that the device of HOFFMAN, which the Examiner considers to be equivalent to the presently claimed ligament reconstruction device, is only a guide system and does not penetrate the bone. Thus, Applicant submits that HOFFMAN does not disclose at least the rear-end (of the device for ligament reconstruction) being configured to drive said tip and connector into a bone which receives ligament reconstruction, as recited in amended claim 1.

Further, Applicant submits that the Examiner continues to be inconsistent in his interpretation of the "tip" of the device for ligament reconstruction.

In setting forth the rejection, the Examiner continues to interpret the "tip" as comprising reference numerals 32, 46, and 54, for the purpose of asserting that the tip includes first and second parallel through-holes (i.e., 32 and 64). However, for the purpose of asserting that the "tip" has a general elliptical cross-section, the Examiner interprets the cross-section as <u>only</u> being a cross-sectional end of the device 46. However, neither 46 nor 54 are driven into bone. Therefore, Applicant submits that the Examiner's interpretation of HOFFMAN is inconsistent.

In other words, Applicant submits that since the Examiner considers the tip to be equivalent to the end of the device (as characterized by the Examiner on page 4 of the Official Action); the cross-section, as purportedly disclosed in HOFFMAN, would be comprised of several geometrical cross-sections having different dimensions. Thus, Applicants submit that HOFFMAN does not disclose "a tip which has a generally elliptical or rectangular cross-section," as recited in claim 1.

In regard to the rejection which relies on HUEBNER as a basis (i.e., which includes the rejection of claim 15), in setting forth the rejection, the Examiner takes the position that HUEBNER discloses the presently claimed tip (which the Examiner considers to be the end of the device provided with holes 59), rear-end (indicated by the Examiner as being 76), and connector (indicated by the Examiner as being 62).

However, contrary to the Examiner's assertions, Applicant again submits that the device of HUEBNER is structurally very different from the presently claimed invention.

In particular, Applicant submits that HUEBNER discloses that the "[g]uide portion 76 may include among others, any structure connected to coupling portion 74 and configured to define guide axis 62. The guide axis may be any path along which a tool or

fastener may be guided physically by the guide portion. Accordingly, the guide axis may be defined by a guide element 60 having a passage, such as a channel, through which a tool or fastener may be advanced axially. The passage may restrict substantial lateral movement of the tool or fastener by having a diameter slightly larger than a tool and/or fastener for which the passage is configured. The guide element may be an integral component of the guide portion, such as an aperture or opening formed in the guide portion, or may be formed by a separate component, such as a tube (or cannula) of any suitable shape and size disposed in a frame 79 of the guide portion. The tube may direct a drill bit, a fastener (such as a bone screw), and/or a driver (such as screwdriver), among others, through the guide element and along guide axis 62 through intervening bone and then to an oppositely situated bone-repair device" (see, paragraph [0041]).

In other words, Applicant submits that similar to the device of HOFFMAN, HUEBNER also discloses a guide system which does not penetrate the bone. Thus, Applicant submits that HUEBNER does not disclose at least the rear-end (of the device for ligament reconstruction) being configured to drive the tip and connector into a bone which receives ligament reconstruction, as recited in amended claim 15.

Further, Applicant submits that "[a] functional limitation must be evaluated and considered, just like any other limitation of the claim, for what it fairly conveys to a person of ordinary skill in the pertinent art in the context in which it is used. A functional limitation is often used in association with an element, ingredient, or step of a process to define a particular capability or purpose that is served by the recited element, ingredient or step." See, In Innova/Pure Water Inc. v. Safari Water Filtration Sys. Inc., 381 F.3d 1111, 1117-20, 72 USPQ2d 1001, 1006-08 (Fed. Cir. 2004).

Accordingly, Applicant respectfully requests that the Examiner clearly explain and indicate how or where HOFFMAN and HUEBNER discloses the rear-end (of the device for ligament reconstruction) being configured to drive the tip and connector into a bone which receives ligament reconstruction (as generally recited in amended claims 1 and 15) in the next Official Action, i.e., should the Examiner decide to maintain the above-noted bases for rejection.

Additionally, in regard to the Examiner's rejection of method claims 10-13, as discussed *supra*, Applicant submit that HOFFMAN and HUEBNER do not disclose at least the presently claimed rear-end (of the device for ligament reconstruction) being configured to drive said tip and connector into a bone which receives ligament reconstruction, and is therefore, incapable of performing the method recited in claims 10-13.

Accordingly, the Examiner is respectfully requested to withdraw the rejection under 35 U.S.C. § 102 and allow all pending claims in the present application.

In the Official Action, the Examiner rejected claims 2, 4-7 and 21 under 35 U.S.C. § 103(a) as being unpatentable over HOFFMAN; and

Claims 16, 18-20 and 22 have been rejected under 35 U.S.C. § 103(a) as being unpatentable over HUEBNER.

Firstly, Applicant again submits that the aforementioned claims are at least patentable due to their respective dependences from claims 1 and 15, and method claim 10, for the reasons noted above. In this regard, Applicant submits that the Examiner has provided no proper reasoning for correcting the above-noted deficiencies in the teachings of HUEBNER.

Applicant further submits that the Examiner's assertion that the combination of elements recited in claims 2, 4-7, 16 and 18-22, only involve discovering obvious optimum or workable ranges, does not provide any teachings which could reasonably be characterized as curing the above-noted deficiencies in the teachings of HUEBNER.

In this regard, Applicant submits that HUEBNER, alone or in any proper combination, does not disclose, inter alia, the tip having a generally elliptical or rectangular cross section elongated in a direction in which the through-holes thereof are juxtaposed, as recited in claim 1.

Further, although the Examiner continues to reject the aforementioned claims as being merely a matter of obvious optimization, Applicant submits that the Examiner still has not made such showing, but has relied on a conclusion of obviousness that is not supported by any evidence or reasoning. Further, the Examiner's assertion that the use of the term "preferable" in the written description somehow indicates that the features recited in claims 2, 4-7, 16 and 18-20 are not critical is unsupported by any factual evidence.

In this regard, Applicant submit that the written description clearly discusses the advantages of the present claimed device for ligament reconstruction.

More particularly, Applicant submits that at least one advantage of the presently claimed invention is that the tip and body portion have a generally elliptical or rectangular cross section rather than a simple round cross section. Therefore, the bone cavity to be formed in the bone has a cross section close to the cross section of an ordinary ligament, so that the outer peripheral surface of the ligament is entirely brought into proximity to the interior surface of the bone cavity. Hence, the ligament can be

bonded to the bone with a greater bonding force in a shorter period of time (see, Page 3, lines 1-6). Contrary to the Examiner's assertions, the applied prior art does not even contemplate the presently claimed cross-section; much less, the advantages associated therewith.

Thus, Applicant submits that it is apparent from the present Specification that the particular geometries of the device for ligament reconstruction, as recited in claims 2, 4-7, 16 and 18-20, will at least have an advantageous effect on ligament bonding.

In regard to the rejection of dependent claims 21 and 22 (which both generally recite a ligament reconstruction device including, <u>inter alia</u>, the entire cross-section of the tip being generally elliptical or rectangular), Applicant submits that the applied prior art does not disclose the features recited in these claims.

In setting forth the rejection, the Examiner acknowledges that the applied prior art does not disclose the above-noted features of claims 21 and 22. Nevertheless, the Examiner asserts that these features are merely obvious choices in design.

Applicant submits that (contrary to the Examiner's assertions) page 15, of the Response filed on May 30, 2007, clearly states that at least one advantage of the presently claimed invention, as recited in the above-noted combination of elements, is that the tip and body portion have a generally elliptical or rectangular cross section rather than a simple round cross section.

Therefore, Applicant submits that the bone cavity to be formed in the bone has a cross section close to the cross section of an ordinary ligament, so that the outer peripheral surface of the ligament is entirely brought into proximity to the interior surface of the bone cavity. Hence, the ligament can be bonded to the bone with a greater bonding

force in a shorter period of time (see, Page 3, lines 1-6, of the present Specification).

Thus, Applicant submits that the features recited in claims 21 and 22 are not obvious design choices, as asserted by the Examiner.

Accordingly, the Examiner is respectfully requested to withdraw the rejection under 35 U.S.C. § 103 and allow all pending claims in the present application.

Further, if the Examiner decides to maintain the aforementioned rejection of claims 2, 4-7, 16 and 18-22, Applicant respectfully requests that the Examiner provide appropriate teaching references disclosing the recited features.

In view of the arguments herein, Applicant submits that independent claims 1 and 15, and method claim 10, are in condition for allowance. With regard to dependent claims 2-9, 11-14 and 16-22, Applicant asserts that they are allowable on their own merit, as well as because of their respective dependencies from independent claims 1 and 15, and method claim 10, which Applicant has shown to be allowable.

Thus, it is respectfully submitted that all of the claims in the present application are clearly patentable over the references cited by the Examiner, either alone or in combination, and an indication to such effect is respectfully requested, in due course.

SUMMARY

Applicant submits that the present application is in condition for allowance, and respectfully requests an indication to that effect. Applicant has argued the allowability of the claims and pointed out deficiencies of the applied reference. Accordingly, reconsideration of the outstanding Official Action and allowance of the present application and all the claims therein are respectfully requested and is now believed to be appropriate.

Applicantsubmits that this amendment is being made to advance prosecution of the application to allowance and should not be considered as surrendering equivalents of the territory between the claims prior to the present amendment and the amended claims. Further, no acquiescence as to the propriety of the Examiner's rejection is made by the present amendment. All other amendments to the claims which have been made in this amendment, and which have not been specifically noted to overcome a rejection based upon the prior art, should be considered to have been made for a purpose unrelated to patentability, and no estoppel should be deemed to attach thereto.

Should the Examiner have any questions, the Examiner is invited to contact the undersigned at the below-listed telephone number.

December 11, 2007 GREENBLUM & BERNSTEIN, P.L.C. 1941 Roland Clarke Place Reston, VA 20191 (703) 716-1191 Respectfully submitted, Katsunori FUTASE

Bruce H. Bernstein Reg. No. 29,027

William Pieprz Reg. No. 33,630